

## **REMARKS**

### **Withdrawn Claims and Cancelled Claims**

Claims 21-48 have been withdrawn from consideration as being drawn to a non-elected species of the invention. Claims 42-48 have been cancelled without prejudice for possible consideration in a continuing application. The Applicant has chosen to maintain the remainder of the withdrawn claims 21-41 in the pending application for possible reinstatement upon the allowance of one or more generic base claims.

### **Claim Rejections – 35 USC §102 and 103**

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Claims 1 and 58 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,397,364 to Kozak et al. (hereafter “the ‘364 patent”) and under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,192,327 to Brantigan (hereafter “the ‘327 patent”). Additionally, claims 1-10, 12, 13, 17-18 and 58 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,514,180 to Heggeness (hereafter “the ‘180 patent”).

Further, claims 14-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over the ‘180 reference in view of U.S. Patent No. 4,703,108 to Silver et al. (hereafter “the ‘108 patent”). Also, claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over the ‘180 reference in view of U.S. Patent No. 5,366,875 to Wozney et al. (hereafter “the ‘875 patent”), and claim 19 was rejected under 35 U.S.C. §103(a) as being unpatentable over the ‘180 reference in view of U.S. Patent No. 5,609,635 to Michelson (hereafter “the ‘635 patent”),

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Independent claims 1 and 58 have each been amended to recite that the two lateral walls each have “a flat lateral surface”, and with the anterior, posterior and lateral walls “cooperating to define a D-shaped spacer body sized and configured to substantially fill the space between the vertebrae with said convexly curved anterior surface of said anterior wall

size and shaped to substantially conform to an anterior aspect of the space between the vertebrae”. As will be discussed below, independent claims 1 and 58, as amended, are submitted to be patentable over each of the cited patent references.

As an initial matter, support for the recitation that the two lateral walls each have a flat lateral surface is found on page 4, lines 14-17 and in Figures 1-3 of the subject application. Support for the recitation regarding the D-shaped spacer body being sized and configured to substantially fill the space between the vertebrae is found on page 4, lines 14-17, page 7, lines 13-15, page 8, lines 8-18, and in Figures 1-3 of the subject application. Additionally, support for the recitation that the convexly curved anterior surface of the anterior wall is sized and shaped to substantially conform to an anterior aspect of the space between the vertebrae is found on page 8, lines 11-14 of the subject application.

With regard to the ‘364 patent to Kozak et al., the interbody fusion device 20 does not include an anterior wall having a convexly curved anterior surface, an opposite posterior wall having a flat posterior surface, and two lateral walls each having a flat lateral surface, with the anterior, posterior and lateral walls cooperating to define a D-shaped spacer body. Even assuming arguendo that the anterior spacer portion 23 defines a convexly curved anterior surface and the posterior spacer portion 22 defines a flat posterior surface, each of the lateral spacer portions 21 clearly do not define a “flat lateral surface”, as recited in independent claims 1 and 58. Furthermore, the anterior, posterior and lateral portions of the fusion device 20 do not cooperate to define “a D-shaped spacer body”, as also recited in independent claims 1 and 58. To the contrary, the fusion device 20 has a kidney bean shape. Moreover, the anterior and posterior spacer portions 22, 23 of the fusion device 20 are not formed integral with the lateral spacer portions 21 to define “a single piece spacer body”, as recited in independent claim 58. To the contrary, the fusion device 20 comprises a multi-piece structure, with the anterior, posterior and lateral portions sized for individual and percutaneous introduction into the disc space, with the spacer portions subsequently assembled within the disc space to form the assembled multi-piece fusion device 20. (See e.g., Abstract and column 5, lines 10-21).

For at least these reasons, the Applicant submits that the ‘364 patent does not teach or suggest each of the elements and features recited in independent claims 1 and 58, as now

amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1 and 58 as being anticipated by the '364 patent and requests allowance of the same.

With regard to the '327 patent to Brantingan, even assuming arguendo that the hemi-oval device 20 illustrated in Figure 2 includes a first wall having a convexly curved surface, an opposite second wall having a flat surface, and two lateral walls each having a flat surface, with each of the walls cooperating to define a D-shaped spacer body, the hemi-oval device 20 still fails to satisfy important structural features recited in independent claims 1 and 58. Specifically, the hemi-oval device 20 is not "sized and configured to substantially fill the space between the vertebrae", as recited in each of the amended independent claims 1 and 58. To the contrary, the hemi-oval device 20 is sized and configured to fill no more than one-half of the disc space. Indeed, a pair of the hemi-oval devices 20 positioned side-by-side would be required to substantially fill the disc space. Moreover, the convexly curved surface of the hemi-oval device 20 is not "sized and shaped to substantially conform to an anterior aspect of the space between the vertebrae", as also recited in each of the amended independent claims 1 and 58. Instead, the convexly curved surface of the hemi-oval device 20 has a relatively tight radius of curvature that is sized and shaped to conform to a lateral aspect of the disc space, and which clearly would not conform to an anterior aspect of the disc space within which the device 20 is inserted.

As should be appreciated, the particular size and shape of the spacer recited in independent claims 1 and 58 is an important aspect of the claimed invention in that such a configuration allows use of a single spacer to support the adjacent vertebrae, while at the same time inhibiting subsidence into the softer cancellous bone of the adjacent vertebrae. As indicated on page 8, lines 12-14 of the present application, the curved anterior wall conforms to the harder cortical bone of the adjacent vertebral bodies, thereby inhibiting subsidence into the softer inner cancellous bone. Additionally, the relatively larger size and shape of the implant recited in independent claims 1 and 58 provides advantages over the much smaller hemi-oval device 20 disclosed in the '327 patent. Specifically, a pair of the hemi-oval devices 20 would have to be positioned side-by-side and engaged with one another to substantially fill the disc space. However, the size and shape of the spacer recited in independent claims 1 and

58 is such that a single spacer may be utilized to support substantially the entire space between adjacent vertebrae.

For at least these reasons, the Applicant submits that the '327 patent does not teach or suggest each of the elements and features recited in independent claims 1 and 58, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1 and 58 as being anticipated by the '327 patent and requests allowance of the same.

With regard to the '180 patent to Heggeness et al., the device 70 illustrated in Figure 24 does not include an anterior wall having a convexly curved anterior surface, an opposite posterior wall having a flat posterior surface, and two lateral walls each having a flat lateral surface, with the anterior, posterior and lateral walls cooperating to define a D-shaped spacer body. Even assuming arguendo that the anterior portion of the outer ring 72 defines a convexly curved anterior surface and that the posterior portion defines a flat posterior surface, each of the lateral portions of the outer ring 72 clearly do not define a "flat lateral surface", as recited in independent claims 1 and 58. Furthermore, the anterior, posterior and lateral portions of the spacer device 70 do not cooperate to define "a D-shaped spacer body", as also recited in independent claims 1 and 58. To the contrary, the spacer device 70 has a kidney bean shape.

For at least these reasons, the Applicant submits that the '180 patent to Heggeness et al. does not teach or suggest each of the elements and features recited in independent claims 1 and 58, as now amended. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1 and 58 as being anticipated by the '180 patent and requests allowance of the same.

Dependent claims 2-20 depend from amended independent claim 1 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 1.

New claims 59-69 have been added to the subject application and are submitted to be patentable for at least the reasons set forth above in support of the patentability of the corresponding independent base claims 1 and 58. Moreover, the subject matter recited in dependent claims 59-69 are patentable over one or more of the cited patent references for

other reasons as well. Additionally, new claims 59-69 are submitted to be fully supported by the subject application. Specifically, claim 59 is supported by the subject matter recited in independent claim 58 and as illustrated in Figures 1-3. Claims 60-62 and 65-67 are supported at page 13, line 23 to page 14, line 5, and in Figures 1 and 2. Claims 63 and 68 are supported by original dependent claim 20. Claims 64 and 69 are supported at page 15, lines 10-15, and in Figure 1.

### CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 1-20 and 58-69.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

Brad A. Schepers  
Reg. No. 45,431  
Krieg DeVault LLP  
One Indiana Square, Suite 2800  
Indianapolis, Indiana 46204-2079  
(317) 238-6334 (voice)  
(317) 238-6371 (facsimile)